K002082

OCT - 6 2000

510(k) SUMMARY

SUBMITTED BY:

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Specialist, Regulatory and Clinical
Spinal Concepts, Inc.
12012 Technology Blvd., Suite 100
Austin, TX 78727

512-918-2700

July 7, 2000

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification name: Pedicle Screw Spinal System
Common/usual name: Posterior Spine Implants
Product classification: Class II
Proprietary name: SpeedLink Transverse Connector

PREDICATE DEVICE

The predicate device is the transverse connector, which was approved as part of the BacFix™ Spinal Fixation System under 510(k)'s K973687 and K983260.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

INDICATIONS FOR USE

The SpeedLink Transverse Connector is intended to be used as a temporary construct that assists normal healing and is not intended to replace normal body structures. The connector is designed as an adjunct to the BacFix® Spinal Fixation System and is intended to stabilize the spinal operative site during fusion procedures. The connector should be removed after fusion.

The Spinal Concepts, Inc. BakFix® ti Spinal Fixation System consists of a combination of components which include rods, hooks, locking wedges, screws and transverse connectors which are indicated to provide temporary stability of the thoracic, thoracolumbar or lumbar spine (T1-S1)

When intended for pedicle screw fixation, implants are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar or sacral spine: Degenerative spondylolisthesis, with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis,

spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range to T1 to the sacrum.

As a pedicle screw system, the BacFix® Spinal Fixation System is intended only for patients: (a) having Grade 3 or Grade 4 spondylolisthesis at L5-S1, utilizing autologous bone graft, having the device fixed or attached to the lumbar spine and intended to be removed after solid fusion is established. Levels of pedicle screw fixation for this indication are from L3 to the sacrum.

When intended for non-pedicle , posterior screw fixation, the system is intended for hook, wire and/or sacral/iliac screw fixation from the thoracic spine to the ileum/sacrum. The indications are:

- Idiopathic scoliosis
- Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spacticty
- Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.
- Spinal fractures (acute reduction or late deformity)
- Degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Neoplastic disease
- Spondylolisthesis
- Spinal stenosis
- Failed previous fusion

DEVICE DESCRIPTION

The Spinal Concepts, Inc. SpeedLink Transverse Connector is a cross-linking component designed for use with the BacFix® Ti Spinal Fixation System which was originally granted marketing clearance via K973687 on March 18, 1998 and subsequently via K983260 on October 21, 1998. The SpeedLink Transverse Connector is manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F-136 and is intended to provide rotational and side-to-side stability to a BacFix® Titanium hook, rod and screw construct, in the case of multi-level constructs or when ever additional stabilization is desired. Use of the SpeedLink Transverse Connector as a construct component during implantation of the BacFix® Ti Spinal Fixation System is at the discretion of the surgeon and is not required when using the BacFix® Ti Spinal Fixation System.

The SpeedLink Transverse Connector utilizes a cam lock connector mechanism to fix the cross-link to the rods. Cam interference is applied by rotating the cam within the link body. The cam deploys progressive interference to the rod until an optimum interference is obtained at the final rotated position.

There are two styles of the SpeedLink Transverse Connector, Fixed and Adjustable, and the delineation refers to the distance between the two rods to be spanned by the connector. The connector accommodates the two diameters of

rods offered in the BacFix® Ti Spinal Fixation System (5.5 and 6.0 mm). All link styles utilize the same cam locking mechanism. There are two styles of Fixed length connectors, Outboard and Inboard, and this refers to the orientation of the cams and the T-handle locking tool. The Fixed length connectors range in distance from 15 to 35 mm in increments of 5 mm. The adjustable length connector can span distances ranging from 39.5 to 80.0 mm.

COMPARISON TO THE PREDICATE DEVICE

The SpeedLink Transverse Connector is significantly equivalent to the previously cleared cross-links approved as part of the BacFix® Spinal Fixation System. All implants are used to treat the same conditions, have the same precautions and contraindications for use, and have equivalent potential for complications. Based upon mechanical testing, indications for use, surgical technique, preproduction quality assurance planning and engineering analysis, Spinal Concepts, Inc. believes that sufficient data exists to reasonably conclude that the SpeedLink Transverse Connector is substantially equivalent to existing legally marketed posterior implants.

DISCUSSION OF NONCLINICAL TESTS

Data comparing the mechanical performance of the SpeedLink Transverse Connector and the predicate device were collected experimentally. Testing quantified the loads required to cause torsional and axial slip of the connector on the spinal rod. Testing also quantified the force required to release the spinal rod from the SpeedLink connector (pullout force). Test data indicated that axial slip and pullout forces were greater with SpeedLink Transverse Connector, and that the SpeedLink meets or exceeds all functional requirements for the stated indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

David Hooper, Ph.D.
Specialist, Regulatory and Clinical Affairs
Spinal Concepts, Inc.
12012 Technology Boulevard, Suite 100
Austin, Texas 78727

Re: K002082
Trade Name: Speedlink Transverse Connector
Regulatory Class: II
Product Code: KWP, MNH, MNI
Dated: August 25, 2000
Received: August 28, 2000

Dear Dr. Hooper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhauser

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INIDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002082

Device Name:

Spinal Concepts, Inc. **SpeedLink Transverse Connector**

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002082

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

When intended for non-pedicle , posterior screw fixation, the system is intended for hook, wire and/or sacral/iliac screw fixation from the thoracic spine to the ileum/sacrum. The indications are:

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